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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,355	06/12/2006	Robert C. Leif	90274U	8971

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/578,355	LEIF ET AL.
	Examiner	Art Unit
	MELISSA PERREIRA	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9 and 11-18* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/11 has been entered.

Claims and Previous Rejections Status

2. Claims 1-6 and 8-18 are pending in the application.

3. The rejection of claims 1-6 and 16 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due the amendment to the claims.

4. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn due the amendment to the claims.

5. The rejection of claims 1-4,6,16 and 17 under 35 U.S.C. 102(b) as being anticipated by Leif et al. (US 6,340,744 B1) is withdrawn.

6. The rejection of claims 8,9,11 and 12 under 35 U.S.C. 102(b) as being anticipated by Leif et al. (US 6,340,744 B1) is withdrawn.

7. The rejection of claims 1-6,16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Leif et al. (US 6,340,744 B1) in view of Mathis et al. (US 4,927,923) is withdrawn.

8. The rejection of claims 8,9,11,12-15 and 18 under 35 U.S.C. 103(a) as being unpatentable over Leif et al. (US 6,340,744 B1) in view of Mathis et al. (US 4,927,923) and in further view of Vallarino et al. (US 5,696,240) is withdrawn.

9. The rejection of claims 1,3 and 4 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 5,696,240 is withdrawn

10. The rejection of claims 1,3 and 4 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4,27 and 34 of U.S. Patent No. 5,373,093 is withdrawn.

11. The rejection of claim 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,750,005 is withdrawn.

Declaration/Affidavit

12. The declaration under 37 CFR 1.132 filed 3/29/11 is sufficient to overcome the rejection of claims 1-6 and 8-18 based upon the statement that the compositions of Leif '744 exist in a micellar organization whereas the composition of the instant claims is a solid composition or a single-phase solution.

Response to Arguments

13. Applicant's arguments with respect to claims 1-6,8,9 and 11-18 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Objection/Rejection Necessitated by the Amendment

Claim Objections

14. Claims 16 and 17 are objected to because of the following informalities: the claim identifiers are incorrect as they state that the instant claims are (new). These claims were previously added in the amendment filed 8/9/10. Appropriate correction is required.

Claim Rejections - 35 USC § 102

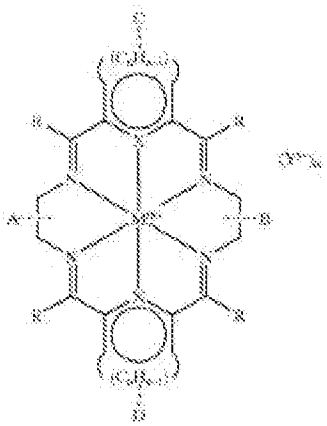
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-4,6,16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Leif et al. (US 6,340,744 B1).

16. Leif et al. (US 6,340,744 B1) teaches of spectrofluorimetrically detectable luminescent compositions comprising a.) at least one energy transfer acceptor lanthanide element macrocycle compound which may be substituted with reactive functional groups (analyte binding species) at which reaction with analytes can take place and has an emission spectrum peak in the range from 500-950 nm; b.) at least

one energy transfer donor compound (abstract; claim 1, column 2, lines 16+; column 8, lines 7-22; column 9, lines 45+; column 10, lines 1-13; column 11, lines 60+). The enhanced luminescence afforded by the composition enables the detection and/or quantitation of many analytes in low concentration without the use of expensive, complicated time-gated detection systems (abstract). The luminescent compositions of the disclosure are combined with a sample containing an analyte in an aqueous solution (column 11, lines 33-45).

17. The energy transfer acceptor macrocyclic compound has the formula (below) wherein M is a metal ion selected from the group consisting of an actinide having atomic number 89-103, etc. that does not include yttrium or gadolinium; R is hydrogen, straight-chain alkyl, etc.; X is selected from the group consisting of nitrogen, sulfur and oxygen which forms a part of a ring structure selected from the group consisting of pyridine, etc.; n is 2 or 3; Y is a negatively charged ion; m is the ionic charge of the metal ion in the macrocyclic complex; y^- is the ionic charge of the counterion in the macrocyclic complex; A,B,C and D are selected substituents selected from the group consisting of hydrogen, straight-chain alkyl, etc. (claim 1; column 2, lines 17-27; column 4).

18. 

19. The luminescent compositions of the disclosure emit energy (enhanced luminescence in the range of 500-950 nm) upon excitation in the range of 200-400 nm (column 3, lines 8-12 and 55-60). The luminescent compositions of the disclosure may further comprise a micelle-producing amount of at least one surfactant and may be lyophilized to form a solid and/or transferred to a non-aqueous medium and measured in the non-aqueous environment or in the dry state (column 2, lines 16-28; column 10, lines 21-34).

20. The luminescent compositions of Leif et al. (US 6,340,744 B1) anticipate the luminescent resonance energy transfer transparent composition of the instant claims as the compositions of Leif et al. (US 6,340,744 B1) may be a solid after lyophilization and or measured in the dry state.

21. Claims 1-4,6,16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Leif et al. (US 6,750,005B2).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

22. Leif et al. (US 6,750,005B2) teaches of a spectrofluorimetrically detectable luminescent composition comprising at least one energy transfer acceptor lanthanide

element macrocycle compound having an emission spectrum peak in the range from 500 to 950 nm and a luminescence-enhancing amount of at least one energy transfer donor compound of yttrium or a 3-valent lanthanide element having atomic number 59-71 (and thus is not necessarily Gd), provided that the lanthanide element of said macrocycle compound and the lanthanide element of said energy transfer donor compound are not identical. The luminescent compositions comprise a micelle-producing amount of least one surfactant. The luminescent compositions can be functionalized wherein the macrocycles are substituted with reactive functional groups at which reaction with analytes can take place (abstract; column 2, lines 18+; column 3, lines 45+; column 4; column 7, lines 16+). The Eu-Macrocycle-Avidin conjugates are attached to agarose beads for solid state luminescence studies and therefore the Eu-Macrocycle-Avidin conjugates are solid (examples IV, VIII).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 1-6 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leif et al. (US 6,340,744 B1) in view of Mathis et al. (US 4,927,923).

25. Leif et al. (US 6,340,744 B1) discloses spectrofluorimetrically detectable luminescent compositions comprising a.) at least one energy transfer acceptor

lanthanide element macrocycle compound which may be substituted with reactive functional groups (analyte binding species) at which reaction with analytes can take place and has an emission spectrum peak in the range from 500-950 nm; b.) at least one energy transfer donor compound as well as that stated above.

26. Leif et al. (US 6,340,744 B1) does not disclose a cryptate.

27. Mathis et al. (US 4,927,923) discloses macropolycyclic rare earth complexes, namely cryptates complexed to a rare earth ion wherein the macropolycyclic rare earth complexes are useful as fluorescent tracers for biological substances in immunological detection or determination techniques using fluorescence. The methods of determination are in homogeneous phases or in a solid phase (column 15, lines 58+; column 16, lines 1-11). The complexes are stable in aqueous media and have excellent selectivity and stability (column 3, lines 63+; column 4; column 7, lines13-25). The excitation of the cryptate rare earth complexes enhances the fluorescence characteristics of a rare earth ion as excitation of an isolated rare earth ion produces only a very weak fluorescence because they generally have low molar absorption coefficients e (abstract; column 3, lines +; column 4, lines 1-37).

28. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the cryptate of Mathis et al. for the macrocyclic chelator of Leif et al. (US 6,340,744 B1) as both compositions can be used in the solid phase to examine the enhancement of the fluorescence of the luminescent compositions for determination techniques as excitation of the cryptate rare earth complexes enhances the fluorescence characteristics of a rare earth ion which generally have low molar

absorption coefficients e. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as enhanced the fluorescence.

29. Claims 1-6 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leif et al. (US 6,750,005B2) in view of Mathis et al. (US 4,927,923).

30. Leif et al. (US 6,750,005B2) discloses a spectrofluorimetrically detectable luminescent composition comprising at least one energy transfer acceptor lanthanide element macrocycle compound having an emission spectrum peak in the range from 500 to 950 nm and a luminescence-enhancing amount of at least one energy transfer donor compound of yttrium or a 3-valent lanthanide element having atomic number 59-71 (and thus is not necessarily Gd), provided that the lanthanide element of said macrocycle compound and the lanthanide element of said energy transfer donor compound are not identical as well as that stated above.

31. Leif et al(US 6,750,005B2) does not disclose a cryptate.

32. Mathis et al. (US 4,927,923) discloses macropolycyclic rare earth complexes, namely cryptates complexed to a rare earth ion wherein the macropolycyclic rare earth complexes are useful as fluorescent tracers for biological substances in immunological detection or determination techniques using fluorescence. The methods of determination are in homogeneous phases or in a solid phase (column 15, lines 58+;

column 16, lines 1-11). The complexes are stable in aqueous media and have excellent selectivity and stability (column 3, lines 63+; column 4; column 7, lines13-25). The excitation of the cryptate rare earth complexes enhances the fluorescence characteristics of a rare earth ion as excitation of an isolated rare earth ion produces only a very weak fluorescence because they generally have low molar absorption coefficients e (abstract; column 3, lines +; column 4, lines 1-37).

33. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the cryptate of Mathis et al. for the macrocyclic chelator of Leif et al. (US 6,750,005B2) as both compositions can be used in the solid phase to examine the enhancement of the fluorescence of the luminescent compositions for determination techniques as excitation of the cryptate rare earth complexes enhances the fluorescence characteristics of a rare earth ion which generally have low molar absorption coefficients e. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as enhanced the fluorescence.

34. Claims 8,9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (US 5,316,909) in view of Leif et al. (US 6,750,005B2).

35. Xu (US 5,316,909) discloses lanthanide chelates (e.g. europium, terbium, etc.) for fluorescence measurement wherein a chelate of a fluorescence-increasing ion is

incorporated to bring about a cofluroescence effect (internal fluorescence effect). The fluorescence intensity of the lanthanide chelate is thereby enhanced when biological active substances are measured (abstract; column 2, lines 33+; column 3, lines 1-37). Xu states that most of the cofluorescence complexes comprise a detergent (surfactant) to form micelles and therefore not all of the cofluorescence complexes require a detergent (surfactant) (column 4, lines 1-32).

36. Biological substances can be labeled directly with very strong fluorescent particles by using a chemical bond or adsorption. After the immunochemical reaction the fluorescence of the particles is measured either in suspension or directly on the surface of a solid support (column 4, lines 33+; column 5, lines 1-9).

37. Xu does not explicitly disclose a single-phase solution or the concentration of the chelate of a fluorescence-increasing ion.

38. Leif et al. (US 6,750,005B2) discloses a spectrofluorimetrically detectable luminescent composition comprising at least one energy transfer acceptor lanthanide element macrocycle compound having an emission spectrum peak in the range from 500 to 950 nm and a luminescence-enhancing amount of at least one energy transfer donor compound of yttrium or a 3-valent lanthanide element having atomic number 59-71 (and thus is not necessarily Gd), provided that the lanthanide element of said macrocycle compound and the lanthanide element of said energy transfer donor compound are not identical as well as that stated above. The concentration of the energy transfer donor compound is present in a concentration greater than the concentration of the energy transfer acceptor macrocycle, such as a range from 1×10^{-5}

to 1 x 10^{-3} moles per liter and provides for cofluorescence (column 9, lines 47-51; column 18, lines 1-8).

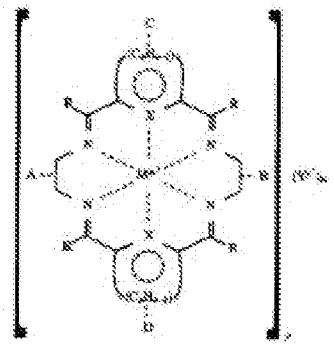
39. At the time of the invention it would have been obvious to one ordinarily skilled in the art that the cofluorescent complexes of Xu are single-phase as they do not necessarily require a detergent (surfactant) to generate miscelles for solid state luminescence.

40. At the time of the invention it would have been obvious to one ordinarily skilled in the art to vary and/or optimize the amount of fluorescence-increasing ion/energy transfer donor compound, such as a concentration range from 1 x 10^{-5} to 1 x 10^{-3} moles per liter, according to the guidance provided by Leif et al., to provide a composition having the desired properties, such as the desired cofluorescence. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

41. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallarino et al. (US 5,696,240) in view of Xu (US 5,316,909) and in further view of Leif et al. (US 6,750,005B2).

42. Vallarino et al. (US 5,696,240) discloses macrocyclic complexes (below) for the method of analysis of a sample containing an analyte. The complexes comprise M is a metal ion selected from the group consisting of a lanthanide having an atomic number 59-71, an actinide having atomic number 89-103, etc.; R is hydrogen, straight-chain

alkyl, etc.; X is selected from the group consisting of nitrogen, sulfur and oxygen which forms a part of a ring structure selected from the group consisting of pyridine, etc.; n is 2 or 3; Y is a negatively charged ion; m is the ionic charge of the metal ion in the macrocyclic complex; y^- is the ionic charge of the counterion in the macrocyclic complex; A,B,C and D are selected substituents selected from the group consisting of hydrogen, straight-chain alkyl, etc. (column 8, lines 32+; column 9; column 11, lines 1+; claim 4). The macrocyclic complexes are further conjugated to biologically active molecules and may be used in analytical procedures, e.g. fluorescent immunoassays, etc. or an injectable solution for administration to a recipient for in vivo observation and/or labeling of a target tissue (column 12, lines 45-62; column 13, lines 1-15; column 19, lines 43-48). The macrocyclic complex may comprise a solid crystalline product that have increased solubility, greater stability, etc. (column 10, lines 37-52; column 13, lines 40-54; column 23, lines 55+).

43. 

44. Vallarino et al. further discloses that the principle of use of the macrocyclic complexes in the field of immunoassays involves the addition of a sensitizer to enhance the fluorescence intensity (column, lines 53+).

45. Europium-macrocyclic complexes are coupled to agarose beads for solid phase immunoassays wherein the biotinylated agarose beads are washed and treated/incubated with the europium-macrocycle-coupled avidin solution and then centrifuged and washed thoroughly to generate the solid europium-avidin/biotinylated beads. The europium(III)-macrocycle-streptavidin complex (solid) was treated with a saturated solution of 4,4,4-Trifluoro-1-(2-thienyl)butane-1-3-dione (thenoyltrifluoroacetylacetone) in the tricine buffer and the mixture irradiated with UV light of 350-360 nm to give an intense red luminescence (example XXIX, especially step 3).

46. Vallarino et al. does not disclose the luminescence enhancing solution of the instant claims or all of the method steps for the instant claims 14 and 15.

47. Xu (US 5,316,909) discloses lanthanide chelates (e.g. europium, terbium, etc.) for fluorescence measurement wherein a chelate of a fluorescence-increasing ion is incorporated to bring about a cofluroescence effect (internal fluorescence effect) as well as that stated above.

48. Leif et al. (US 6,750,005B2) discloses a spectrofluorimetrically detectable luminescent composition comprising at least one energy transfer acceptor lanthanide element macrocycle compound having an emission spectrum peak in the range from 500 to 950 nm and a luminescence-enhancing amount of at least one energy transfer donor compound of yttrium or a 3-valent lanthanide element having atomic number 59-71, provided that the lanthanide element of said macrocycle compound and the

lanthanide element of said energy transfer donor compound are not identical as well as that stated above.

49. Leif et al. discloses a method for analysis of a sample suspected of containing at least one analyte, frequently a biologically active compound comprising a.) contacting said sample with a functionalized complex of a metal in a reaction medium under binding conditions, wherein the reaction medium in which a sample containing or suspected of containing an analyte is an aqueous solution; b.) adding a luminescence-enhancing amount of at least one energy transfer donor compound; c.) subjecting the reaction medium to excitation energy in the range of 200-400 nm, whereby enhanced luminescence in the range of 500-950 nm is generated; d.) monitoring said luminescence of the reaction medium to measure in said sample at least one of the following: (1) presence and/or concentration of said conjugate; (2) presence and/or concentration of the product of the interaction of said complex with said binding material (analyte); (3) presence and/or concentration of the product of the interaction of the conjugate with the binding material (analyte) (column 2, lines 28-36 and 53+; column 3, lines 1-20; column 11, lines 33-45). The enhanced fluorescence composition of the invention formed in an aqueous micellar organization can be dried and/or transferred into an aqueous medium and measured in the non-aqueous environment or in the dry state (column 15, lines 13-17).

50. The luminescent compositions can be used for the method for analysis of a sample suspected of containing at least one analyte wherein the Eu-Macrocycle-Avidin conjugates (solid) are treated with a cofluorescence matrix containing Gd(III). The

beads immediately displayed strong luminescence upon irradiation (column 23, Example VIII).

51. At the time of the invention it would have been obvious to one ordinarily skilled in the art to incorporate a fluorescence-increasing ion chelate (luminescence enhancing solution), such as that of Xu with the macrocyclic complexes of Vallarino et al. to bring about a cofluroescence effect (internal fluorescence effect) for the fluorescent immunoassays of Vallarino et al. as Vallarino et al. already teaches that the enhancement of the fluorescence intensity of the macrocyclic complexes in the field of immunoassays involves is advantageous. Therefore, the inclusion of a fluorescence-increasing ion chelate would predictably provide for a cofluroescence effect (internal fluorescence effect).

52. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize solid support europium-macrocycle-complexes for the method for analysis of a sample suspected of containing at least one analyte as Leif et al. teaches that a combined functionalized metal complex (e.g. solid support europium-macrocycle-complexes of Vallarino et al.) and luminescence-enhancing amount of at least one energy transfer donor compound (e.g. Xu) provides for enhanced luminescence and enables the detection and/or quantitation of many analytes in low concentrations without the use of expensive, complicated time-gated detection systems via a.) contacting said sample with a functionalized complex of a metal in a reaction medium under binding conditions, wherein the reaction medium in which a sample containing or suspected of containing an analyte is an aqueous solution; b.) adding a

luminescence-enhancing amount of at least one energy transfer donor compound; c.) subjecting the reaction medium to excitation energy in the range of 200-400 nm, whereby enhanced luminescence in the range of 500-950 nm is generated; d.) monitoring said luminescence of the reaction medium to measure in said sample at least one of the following: (1) presence and/or concentration of said conjugate; (2) presence and/or concentration of the product of the interaction of said complex with said binding material (analyte); (3) presence and/or concentration of the product of the interaction of the conjugate with the binding material (analyte).

Conclusion

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 7-4 M, 7-4 T, 6 Th, 7-4 F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa Perreira/
Examiner, Art Unit 1618